# External review systems for radiation oncology facilities – clinical audit versus other review systems

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SUMMARY

**BACKGROUND:** Between 1996 and 1999 project team of ExPeRT, catalogued four external review systems of health care facilities in the European Union and countries associated with EU.

**AIM:** The aim of this paper is a/ to identify and compare currently existing external review systems for radiation oncology facilities and b/ to distinguish main differences between clinical audit and other external evaluation models and c/ to identify where those models are currently used in European Union member states.

**MATERIALS AND METHODS:** Based on the literature review and the survey conducted between January and April 2007 among representatives of 67 national societies (for diagnostic radiology, radiotherapy and nuclear medicine) in European Union member states, the analysis of existing external review systems in radiation oncology was performed. Relevant information about purpose, scope and methodology of evaluation process for those systems were surveyed.

**RESULTS:** The response to the questionnaire was 72%. Only a few countries did not supply any reply in spite of repeated enquiries to several recipients. Six main categories of systems aiming at measuring the quality of service management and delivery were identified: professional peer review –based schemes, hospital accreditation, accreditation in terms of ISO standards, award seeking, certification by International Standards Organization, and clinical audit.

**CONCLUSIONS:** Though the methodology and terminology of the five main external review systems differ, a constant movement towards collaboration and convergence of those models has been observed. Due to the social, political, and economical aspects of each European country, the different audit systems have been implemented either on voluntary or mandatory basis.

**KEY WORD:** accreditation, certification, clinical audit, quality award, peer review, radiation oncology

## BACKGROUND

Between 1996 and 1999 project team of ExPeRT (External Peer Review Techniques Project founded by the EC), catalogued the range of external review systems of health care facilities in the European Union and countries associated with EU [1, 2].

All of those systems (peer review, accreditation, certification, award seeking model) are continuously implemented, adopted and improved by many organizations and governments around the world. Accreditation (originated in USA in 1917) and certification (originated in UK in 1947, popularized among health care organizations within last 10 years due to its international recognition, universality, applicability and suitability) are most commonly used systems. Less popular are EFQM excellence model (introduced in Europe in 1988) and peer-review based scheme (visitatie – implemented in the Netherlands by medical associations in 1992). [3]

All of those systems are based on PDCA cycle[1] (except for EFQM based on RADAR cycle[2]) and are characterized by three crucial activities:
– the development of standards,
– the selection, training and monitoring of evaluators (auditors, visitors), and
– the evaluation process with common features such as: process initiation by the institution, self-assessment, agenda or audit plan, evaluation visit, trained evaluation team, report and evaluation of findings.

Though the methodology and terminology of the four main external review systems differ, a constant movement towards collaboration and convergence of those models has been observed, as the ISO model can be easily embedded in an accreditation or EFQM approach. Peer review is the closest to accreditation, and clinical audit as they both refer to health care, whereas ISO and EFQM touch mainly upon the managerial and organizational conditions under which care processes are executed. Moreover ISO based certification, mostly due to its universal nature is most commonly absorbed and adapted, being a core or a framework of existing quality evaluation systems, programs or models [4].

## AIM

The aim of this paper is a/ to identify and compare existing external review systems for radiation oncology facilities and b/ to distinguish main differences between clinical audit and other external evaluation models and c/ to identify where those models are currently used in European Union member states.

## MATERIALS AND METHODS

Based on the literature review and the survey conducted between January and April 2007 among the representatives of 67 national societies (for diagnostic radiology, radiotherapy and nuclear medicine) in European Union member states, the analysis of existing external review systems in radiation oncology was performed. Relevant information about purpose, scope and methodology of evaluation process for those systems were surveyed.

## RESULTS

The response to the questionnaire was 72 %. 6 EU countries (Greece, Slovenia, Slovakia, Malta, Latvia, Estonia) out of 25 did not supply any reply in spite of repeated enquiries to several recipients.

Six main categories of systems aiming at measuring the quality of service management and delivery in radiation oncology were identified: (1) professional peer review –based schemes, (2) hospital accreditation, (3) accreditation in terms of ISO standards, (4) award seeking such as European Quality Award and their national variants (i.e. European Foundation for Quality Management (EFQM) Excellence Model), (5) certification by International Standards Organization (ISO), and (6) clinical audit.

Clinical audit, as defined in the EC directive 97/43/EURATOM [5], has certain similarities with the above mentioned external evaluation systems (especially with the peer review model - Visitatie). However, it is of high importance to understand that clinical audit is different from these other systems: it differs in its objective, scope, method, impact and use, as it was designed for different purpose. These points for clinical audit are compared in detail with the other review systems in Table 1.

## CONCLUSIONS

Due to the many similarities with other review systems, clinical audits should be established and developed in a way which minimizes unnecessary overlap, or duplication of efforts, with the other systems. The key factors to avoid the overlap or duplication can be distinguished as follows:

General:
– Perform audit both internally and externally on regular basis.

Focus of assessment:
– Concentrate on organizational, physical, technical, clinical and safety aspects of the service delivery.
– Concentrate on detailed and not overall information/feedback on the performance of clinical procedures from the evidence-based point of view.

[1]PDCA – plan, do, check, act cycle model proposed by W.E. Deming

[2]RADAR – results, approach, deploy, assess and review (modification of PDCA cycle model)

**Table 1**. Comparison of external audit systems

| | External audit system | | | | | |
|---|---|---|---|---|---|---|
| | **Peer review** | **Hospital accreditation** | **Accreditation in terms of ISO standards** | **Award seeking (EFQM)** | **ISO certification** | **Clinical audit (in terms of EC directive 97. 43. EURATOM)** |
| **Purpose** | Systematic review, visitation, Visitatie in Dutch. Standard based on on-site surveys conducted by health care professionals in order to assess the clinical practice and performance, professional development organization of the care process, and its results aimed at improving the quality of patients care and exchanging ideas. It directs its attention to appropriateness of service delivery provided by medical practitioners. Does not award a certificate. | Systematic assessment of a whole organization (hospital) or specialty-specific areas (in UK), against explicit standards for the purpose of recognition of service delivery. Performed by a national or regional accreditation body.<br>1 to 3 year accreditation of organization and health service delivery confirming compliance with accreditation standards.<br>Awards a certificate. | Systematic assessment of an organization against international ISO standards for the purpose of recognition of competence of an organization. In medical field accreditation is based on laboratory quality standards and assess the competence of medical laboratories) units to run clinical examinations. Performed by a national accreditation body.<br>Accreditation is valid for 2-5 years including annual surveillance visits to ensure that organisation constantly conforms to the accreditation requirements.<br>Awards a certificate. | Also called management excellence model. Assessment of organization's management against performance standards for service industries in specific areas (in health care: such as clinical results, patients satisfaction, administration and staff management). It provides conceptual framework, which is used both as a self-assessment tool and an external review to achieve the quality award.<br>Award of excellence to the organization and its management or self-assessment of the organization. | Assessment of specific aspects of services incl. health services in the context of quality of system, processes and administrative procedures, rather than clinical results or outcomes. Addresses mainly the managerial processes surrounding clinical decision making.<br>Mostly used in more technical) industrial departments. Performed by accredited certification body. Examines designated quality, focusing on how the institution objectives are achieved rather than the institution as a whole meets the needs of its patients. However it verifies if the organization stays in compliance with existing laws and regulations.<br>3 year certification of processes or management system of the whole organization confirming compliance with ISO standards | Systematic and structured control, examination or) and review of medical procedures (used for diagnosis and treatment), the use of resources, and the resulting outcomes for the patient [6]; against agreed standards; for the improvement of quality of medical services through a systematic analysis which proves that practice, procedures and outcomes are comparable with develop standards.<br>It can be of various types and levels, either reviewing specific critical parts of RADIOLOGICAL process (partial audit) or assessing the whole process (comprehensive audit). [7]<br>Performed by national, regional, independent or governmental body. Can also be carried out by international organizations (e.g. IAEA) |
| **Scope** | Care process and its organizational aspects: care delivered, staffing levels, education, facilities, procedures [9] | 1. access to care<br>2. continuity of care<br>3. patient and family rights<br>4. assessment of patients<br>5. care of patients<br>6. patients and family education<br>7. quality management and improvement<br>8. governance, leadership and improvement<br>9. facility management and safety<br>10. staff education and management<br>11. management of information<br>12. prevention and infection control | Management requirements<br>1. organization, management and quality management system<br>3. document and record control<br>4. review of contracts<br>5. subcontracting, external services and supplies<br>6. advisory services<br>7. resolution of complaints, identification and control of non-conformities, corrective and preventative actions, continual improvement<br>9. internal audits and management review<br>Technical requirements<br>1. personnel<br>2. accommondation<br>3. equipment<br>4. pre-examination, examination and post-examination procedures, reporting results | The management of the organization and its:<br>1. leadership<br>2. policy and strategy<br>3. people<br>4. partnership and resources<br>5. processes<br>6. customer results<br>7. people results<br>8. society results<br>9. key performance results [8, 9] | Quality management system:<br>1. aim of the organization<br>2. structure of the organization<br>a) responsibility<br>b) organizational relationship<br>c) departmental infrastructure<br>d) qualification of staff<br>3. obtaining and maintaining means and materials for service delivery<br>a) purchasing<br>b) demonstrating its ability to consistently provide product that meets customer and applicable regulatory requirements<br>c) safety and fitness for clinical use<br>d) documentation and records | Clinical aspects of care and treatment process incl.<br>1. procedures for diagnosis and treatment<br>2. the use of resources<br>3. the resulting outcomes<br>4. the impact upon the quality of life of the patient.<br>It covers in particular: structure (facilities, equipment, environment etc.), processes (diagnosis, qualification, treatment and follow-up etc.) and outcomes of treatment (results of treatment, survivor rate). It addresses to organizational, physical-technical and clinical aspects of service delivery. |

**Table 1**. Cont.

| | External audit system | | | | | |
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| | | | 5. assuring quality of examinations | | e) equipment replacement<br>f) inspection and testing<br>g) control of inspection, measuring and test equipment<br>h) control of non-conformities<br>i) corrective and preventive actions<br>j) handling, storage, packaging, preservation and delivery<br>4. process control<br>5. quality audits<br>6. training – knowledge and skills [10, 11, 12] | |
| **Auditors** | Visitors: clinical and interdisciplinary team of registered specialists for at least 5 yrs, independent of the clinical staff being surveyed. Additionally in the Netherlands with the completion of 1 day training conducted by CBO – National Organization for QA in Hospitals | Surveyors: multidisciplinary team of health professionals experienced in health care sector (doctors, nurses, administrators), with minimum 2-5 years experience in senior managerial position, practicing in a health care facility, after initial and ongoing update training in the field of accreditation | Assessors: multidisciplinary team of health professionals experienced in health care sector (doctors, nurses, physicists), with good experience in discipline, practicing in a health care facility, and quality professionals (lead assessors), after initial and ongoing update training in the field of accreditation. | Assessors: academics and quality professionals or experienced and currently practicing managers. | Auditors: experts in the ISO norm (not in a particular field or type of organization), professionals with necessary education, training, knowledge and experience for performing certification (minimum 20 days auditing experience, analytical skills, language fluency, management capabilities, at least 4 years full time appropriate practical work place experience, 2 years in QA activities, 4 audits as a trainee auditor, trained, assessed and certified by externally recognized training bodies i.e. IRCA – International Register of Certificated Auditors). Experience in health care sector is not required as they are supported by experts with sufficient experience and knowledge in the field. | Auditors: independent clinical experts, registered and trained in clinical audit specialists, (for radiotherapy: radiation oncologist, RTT, medical physicist, engineer; for diagnostic imaging: radiologists, radiation technologist, medical physicist, engineer, for nuclear medicine: specialist in nuclear medicine, radiation technologist, nurse, engineer) appointed by external commission or party<br>Add QUATRO as an example |
| **Methodology of evaluation process** | 1. request an evaluation<br>2. questionnaire to identify the institution's aspects of professional performance, giving the visitation committee an opportunity to and discuss key quality issues with the staff members before the evaluation visit | 1. request an evaluation<br>2. questionnaire to identify the institution eligibility, its structure, size, nature, number of employees, demographic, biographic data etc. to plan the size and composition of the evaluation team, fee for accreditation based on number of days for visit. | 1. request an evaluation<br>2. questionnaire to identify the institution eligibility, its structure, size, nature, number of employees, demographic, biographic data etc. to plan the size and composition of the evaluation team, fee for accreditation based on number of days for visit. | 1. request an evaluation<br>2. self-assessment as a comprehensive, systematic and regular review of structure, processes and outcome, which allows he organization to identify its strengths and weaknesses determining whether the institution may be eligible to compete for an award. | 1. request and evaluation<br>2. questionnaire to identify the institution eligibility its structure, number of employees, processes under evaluation, to plan the size of the auditing team, fee for audit based on number of days for audit | Evaluation process , organized in a cycle consists of the following stages:<br>1. identifying the issue to be audited – i.e. self evaluation questionnaire,<br>2. setting the standard, |

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| | External audit system | | | | | |
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| **Methodology of evaluation process** | 3. agenda of visit composed by the practitioner being visited<br>4. review – duration 1-2 days depending on the number of practitioners being visited or the number of locations. Peers evaluate circumstances under which clinical practice take place by:<br>a) documentation: availability of guidelines, patients medical records etc.<br>b) observation<br>c) structured interviews: treatment outcomes, evaluation of patients' satisfaction, staff collaboration<br>d) feedback session – suggestions for improvement<br>5. written report – (confidential) consists of a description of the clinical department, positive and negative findings and recommendations for improvement<br>6. evaluation of findings<br>7. the return-visit mostly every 5 years, the facility is reviewed by another team of visitors to establish degree to which recommendation and suggestions have been followed and implemented. | 3. self assessment by the institution under evaluation to state) grade its compliance with standards.<br>4. timetable and agenda of visit agreed by the organization<br>5. visit prior the formal evaluation (on request) – completed with rather verbal recommendations and guidance<br>6. formal evaluation visit – duration depending on the size, complexity or nature of the organization:<br>a) review of documentation<br>b) interviews<br>c) sample of medical and other records<br>d) visit-observations<br>e) feedback<br>7. written report – with compliance and non-compliance with explicit standards including is numerical or descriptive grading against the standards.<br>8. evaluation by the accreditation committee (visitors may take part) which makes the decision to accredit the organization, based on the report with graded compliance<br>9. accreditation – valid for 3, 2 or 1 year or non-accreditation<br>10. appeal procedure<br>11. publication of a list of accredited institutions<br>12. interim visits – to review progress in the implementation of the quality action plan and recommendations | 3. self assessment by the institution under evaluation to state) grade its compliance with standards.<br>4. timetable and agenda of visit agreed by the organization<br>5. preliminary visit prior the initial assessment visit to assess the readiness of organization for initial assessment<br>6. initial assessment visit – duration depending on the size, complexity or nature of the organization:<br>a) review of documentation<br>b) interviews<br>c) sample of medical and other records<br>d) visit-observations<br>e) feedback<br>7. written report – with compliance and non-compliance with international accreditation standards including numerical or descriptive grading against the standards.<br>8. evaluation of assessment results by the independent accreditation committee or management of accreditation body which) who makes the decision to accredit the organization<br>9. accreditation – valid for 2-5 years (depending on the procedures of national accreditation body) or non-accreditation<br>10. appeal procedure<br>11. publication of a list of accredited institutions<br>12. surveillance visits – to assess the constant fulfillment of accreditation requirements and effectiveness of corrective action of earlier visit's non-compliances | 3. feedback information to EFQM, on activities resulting from self assessment, which must be closely aligned with EFQM award assessment criteria.<br>4. visit<br>5. feedback written report – provides a list of strengths and areas for improvement under each criterion addressed in the application. The assessor's scoring profile is given together with comparative scoring of other applicants for the award.<br>6. evaluation – by the evaluation committee based on the report with graded compliance<br>7. Institution awarding | 3. presentation of evidences of self preparation documentation (i.e. quality manual, internal audits reports)<br>4. audit plan agreed by the organization<br>5. pre-audit (on request) to determine the scope of the audit, make initial review<br>6. audit – duration depending on the size, complexity or nature of the organization<br>a) opening meeting – introduction, review of the scope and objectives of the audit, summary of procedures used in audit.<br>b) documentation review and examination<br>c) interviews<br>d) observations<br>e) records review<br>f) closing meeting – to present conclusions prior the report<br>7. written report – contains details included in the audit plan, documentation against which the assessment was made, observations of major) minor non-conformities or areas which did not comply with the agreed standards, protocols, procedures and the auditors' judgment of the level of compliance.<br>8. evaluation by the certification body (auditors do not take part) which makes the decision to certify the audited party based on the report with graded compliance<br>9. certification – valid for 3 years in case of positive decision<br>10. re-audit – in case of negative decision<br>11. publication of a list of certified institutions<br>12. interim audits – biannual or annual on agreed aspects of quality system. | 3. measuring the quality and checking the results against the standard set (physical, technical measurements and tests documents and records review and sampling, interviews of the staff)<br>4. identifying whether any change is needed,<br>5. deciding strategies for change,<br>6. implementing necessary changes,<br>7. monitoring the effect of the change against the standard – re-audit.<br><br>The process continue round the cycle again if the standard has not been reached or if core standards are to be on a continuous basis, or new standards has been set. |

**Table 1**. Cont.

| | External audit system | | | | | |
|---|---|---|---|---|---|---|
| | Peer review | Hospital accreditation | Accreditation in terms of ISO standards | Award seeking (EFQM) | ISO certification | Clinical audit (in terms of EC directive 97/43/ EURATOM) |
| Occurrence in Europe | The Netherlands, Finland, Sweden United Kingdom, Belgium, Ireland | France, Italy, Germany, Finland, Poland, UK, Portugal, Spain, The Netherlands, Switzerland, Sweden, Ireland, | According to new EU legislation all EU countries shall arrange national accreditation system, in most of the European countries there is an accreditation body who accredits medical laboratories) organizations | The Netherlands, Denmark, Finland, Norway, Sweden, United Kingdom, Ireland | Poland, Germany, Switzerland, Austria, Denmark, Finland, France, Italy, Luxembourg, The Netherlands, Norway, Sweden, United Kingdom, Spain, Ireland | Poland, Finland, Italy, United Kingdom, The Netherlands, Czech Republic, Ireland, Lithuania |

– Make use of the quality system documentation for the assessment of clinical audit items but do not focus on checking the conformance of the quality system to a quality standard.
– Put much emphasis on a dynamic quality assurance and quality improvement.
– Put more emphasis on goal setting, analysis of the process and planning the improvement.
– Focus on recording and improvement of practice.
– Measure changes in practice to effect change.

Criteria for assessment
– Avoid limitation to minimal standards or norms.
– Assess the practice against sufficient criteria of good clinical practice given e.g. at national or international level
– Provide indicators and standards of good clinical practice which audited organization can refer to.
– Review and update standards systematically, according to the latest evidence based medicine, current results of research, benchmarking.

Practical implementation
– Give aims and an objectives, where an aim is a one-sentence description of what is to be achieved by the audit and an objective is a statement of how a particular factor is to be investigated to contribute to the overall aim of the audit.
– Provide auditors with good knowledge and clinical experience in the field of application to be audited,
– Follow workflow and patient flow, conduct interviews with staff, review or perform measurements and control tests (physical, technical), review documentation and records,
– Assess the appropriateness of the selection of examinations or treatments for patients or the health outcomes,
– Involve anonymous patient data in the audit process (e.g. the quality of the referrals for a sample of patients).

## Implementation of audit systems in Europe

Due to the social, political, and economical aspects of each European country, the different audit systems presented above have been implemented either on voluntary or mandatory basis. For instance, in radiotherapy [13, 14]. some states such as Austria, Belgium, Finland, France, Italy, Germany, the Netherlands, UK and Poland have comprehensive legislation on the management of health care quality including the uptake of external audit system (either accreditation, ISO certification, peer review or clinical audit). For example, Belgium (since 1987), Italy and France have legislation (passed in 1997) for governmental accreditation schemes, Austria requires implementation of quality assurance system in health care organizations (law passed in 1993), Poland on the other hand has legislation (passed in 2001) for certification based on ISO norm and clinical audits (passed in 2005)

in radiation oncology, radiology, nuclear medicine and laboratory medicine.

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